

### REMARKS

Upon entry of the amendments and new claim, claims 1-4, 6-11, 16-17, 19-29, 31-37, 39-42, 44-57, 59-61 and 72-75 will be pending.

Claims 1, 25-26, 44-45 and 60 have been amended; claims 43, 62-63, 65-66 and 68-69 have been canceled; claims 5, 12-15, 38, 64, 67 and 70-71 were previously canceled; and claims 18, 30 and 58 were previously withdrawn.

The amendments to the claims are fully supported in the specification and claims as originally filed. Accordingly, no new matter has been added and entry of the amendment is respectfully requested.

#### **I. Amendment to the Claims**

Claims 1, 25-26, 44-45 and 60 have been amended.

The claims have been amended to better define the metes and bounds of the claimed subject matter. For example, claim 1 has been amended to recite "a set of primers, comprising at least 8 primers...(claim 1)," as such Applicants are claiming the *entire* set of 8 primers and not just a single primer in the set.

Claim 1 has also been amended to define a homolog sequence: "wherein the homolog sequence is a sequence having high sequence identity to the PKD1 gene sequence." Support for this amendment can be found on page 2, paragraph [0006].

Claims 25-26, 44-45 and 60 have been amended to include the entire set of the same 8 primers as in claim 1, thus further defining the metes and bounds of these claims.

Accordingly claim 1 and all claims dependent on claim 1, and claims 25, 44 and 60 and all claims dependent therein, are in condition for allowance, and such is respectfully requested.

#### **II. Restriction/Election**

According to the Office Action, Applicants by amending certain claims (e.g., claim 20), have allegedly waived the original restriction requirement and requirement for sequence election; hence claim 20 should be withdrawn and only considered for rejoinder at the time of allowance.

Applicants submit that claim 20 is not being withdrawn because Applicants made no further amendments to claim 20 in the response filed November 23, 2004 to the Office Action mailed August 23, 2004. Since, no changes were made to claim 20, claim 20 still contains originally elected subject matter, and was in the group of elected claims which received an action on the merits in the first Office Action mailed January 29, 2004.

Accordingly, claim 20 is pending and the responses below incorporate and are with respect to claim 20 as well as all other pending claims.

### **III. Rejections Under 35 U.S.C. §103(a)**

The claims are variously rejected as being allegedly unpatentable over Klinger et al. (U.S. Pat. No. 6,654,170; hereinafter, "Klinger"):

Claims 1-7, 20-22, 25, 31, 37-39, 43-44, 46-49, 59 and 62 stand rejected over Klinger;

Claims 16-17, 19 and 40-42 stand rejected over Klinger in view of Stefano;

Claims 8-15, 26, 28-29, 54, 68-72 and 74 stand rejected over Klinger in view of Buck;

Claims 27, 53, 55, 60-61, 73 and 75 stand rejected over Klinger in view of Buck and Shapira;

Claims 32-33 and 35-36 stand rejected over Klinger in view of Buck and Sathe;

Claims 50-52 stand rejected over Klinger in view of Iliff;

Claims 55-57 stand rejected over Klinger in view of Buck, Shapira and Sathe;

Claims 63-66 stand rejected over Klinger in view of Ahern; and

Claim 34 stands rejected over Klinger in view of Buck and Koster.

Applicants respectfully traverse these rejections as follows.

Claims 43, 62-63, 65-66 and 68-69 have been canceled. Claims 5, 12-15, 38, 64, 67 and 70-71 were previously canceled. Hence, rejection of claims 38 and 43 over Klinger; rejection of

claims 12-15 and 68-69 over Klinger in view of Buck; and rejection of claims 63-66 over Klinger in view of Ahern are moot with respect to these claims (38, 43, 12-15, 63-66 and 68-69).

Claims 1, 25-26, 44-45 and 60 have been amended, and out of these claims, claims 1, 25, 44 and 60 are independent claims. Hence, claims dependent on claims 1, 25, 44 and 60 are likewise affected.

Claims 1, 25-26, 44-45 and 60 have been amended, per the suggestion of the Examiner in the October 22, 2004 interview (i.e., inclusion of the "entire set of 8 primers" could obviate the rejection to the claims). However, the claims were still unallowable in the response filed November 23, 2004 because according to the Office Action (page 23) the claims were indefinite due to the recitation of: "set of primers, comprising primers" and "wherein a primer of said set."

The claims have been further amended such that the composition claim 1 unambiguously recites "[a] set of primers, comprising at least 8 primers", wherein the primers selectively hybridize to the PKD1 gene sequence and not a PKD1 gene homolog sequence, "wherein the homolog sequence is a sequence having high sequence identity to the PKD1 gene sequence." Hence, the claimed primers selectively hybridize to the PKD1 gene and not to its homolog, although the PDK1 gene and its homolog share a high sequence identity.

The method claims have been further amended and recite methods of detecting a PKD1 gene (claim 25), or identifying a subject at risk for a PKD1 associated disorder (claim 44), or diagnosing a PKD1 associated disorder (claim 60) using "[a] set of primer pairs, the set consisting of primer pairs that selectively hybridize to SEQ ID NO: 1 and amplify a portion of SEQ ID NO: 1 comprising about nucleotides 2043 to 4290; nucleotides 17907 to 22489; nucleotides 22218 to 26363; nucleotides 26246 to 30615; nucleotides 30606 to 33957; nucleotides 36819 to 37140; nucleotides 37329 to 41258; nucleotides 41508 to 47320..."

The above amendments clearly define the metes and bounds of the claimed invention and are not obvious over Klinger and/or Klinger in view of Stefano (density arrays), Buck (every primer has a reasonable expectation of success), Shapira (amplifying nucleic acids using nested primers), Sathe (single stranded conformation polymorphism or SSCA or SSCP), Iliff (disease

management system), Ahern (biochemical reagents to form kits) and Koster (Sanger sequencing using nested primers).

The claimed invention is not obvious over Klinger because the primers as set forth in Klinger are not capable of detecting, identifying, and/or diagnosing a PDK1 gene over that of a PDK1 gene homolog. For example, the 5' and 3' regions of the primers in Klinger would be expected to hybridize to both the PKD1 gene and a PKD1 gene homolog, wherein the homolog shares a high sequence identity to the wild-type or authentic gene.

Thus, the primers taught by Klinger cannot selectively hybridize to *just* the PKD1 gene, and a *prima facie* obviousness of the claimed invention has not been established because not all the claim limitations are taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Further, if an independent claim (e.g., claim 1, 25, 44 and 60) is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, the claimed invention is not obvious over Klinger alone, or combined with Stefano, Buck, Shapira, Sathe, Iliff, Ahern and/or Koster.

Accordingly, withdrawal of the pending claims (1-4, 6-11, 16-17, 19-29, 31-37, 39-42, 44-57, 59-61 and 72-75) which are variously rejected under 35 USC § 103(a) is respectfully requested.

#### **IV. Rejection Under 35 U.S.C. §112, first paragraph (written description)**

Claims 1-4, 6-11, 16-17, 19-29, 31-37, 39-57, 59-63, 65-66, 68-69 and 72-75 are rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to describe in the specification in such a way as to convey to one skilled in the art that Applicants were in possession of the claimed invention. Applicants respectfully traverse this rejection as follows.

According to the Office Action, the recitation of “at least ten contiguous nucleotides” and “hybridizes to a nucleotide sequence flanking and within fifty nucleotides” are not

sufficiently described, and that the specification allegedly provides insufficient written description to support the genus encompassed by the claim.

Claims 43, 62-63, 65-66 and 68-69 have been canceled, and claim 20 has been withdrawn, thus the rejection is moot as to these claims. Hence, Applicants address the rejection as it pertains to pending claims: 1-4, 6-11, 16-17, 19-29, 31-37, 39-42, 44-57, 59-61 and 72-75.

Applicants submit that the pending claims are sufficiently described in the specification because the claims refer to, and recite, the target sequences of SEQ ID NO:1, the PKD1 gene. Support for primers which selectively bind to the PKD1 gene is found throughout the specification, claims as originally filed, and Example 1. Also, the claims recite that the primers selectively hybridize to the PDK1 gene “under highly stringent conditions”. Support for these stringent conditions can be found on page 28, paragraph [0056] and page 30, paragraph [0061]. Hence, the recitation of “at least ten contiguous nucleotides” and “within fifty nucleotides” are sufficiently described in the specification, and in the claims as originally filed, because “at least ten contiguous nucleotides” and “sequence flanking and within fifty nucleotides” are with reference to SEQ ID NO:1, the PKD1 gene 1.

Accordingly, withdrawal of the rejection of pending claims 1-4, 6-11, 16-17, 19-29, 31-37, 39-42, 44-57, 59-61 and 72-75 under 35 USC § 112, second paragraph is respectfully requested.

**V. Rejection Under 35 U.S.C. §112, second paragraph (indefiniteness)**

Claims 1-4, 6-11, 16-17, 19-29, 31-37, 39-57, 59-63, 65-66, 68-69 and 72-75 are rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection as follows.

According to the Office Action, the claims are allegedly indefinite over the recitation of “a set of primers, comprising primers (page 23 of the Office Action)”.

Claims 43, 62-63, 65-66 and 68-69 have been canceled, thus the rejection is moot as to these claims. Hence, Applicants address the rejection as it pertains to pending claims: 1-4, 6-11, 16-17, 19-29, 31-37, 39-42, 44-57, 59-61 and 72-75.

Claims 1, 25-26, 44-45 and 60 have been amended as discussed above. The claims have been amended to clearly recite that the “entire set of 8 primers” is claimed and not just a primer within the set. Again, as per the telephonic interview of October 22, 2004, the Examiner suggested that the inclusion of the “entire set of 8 primers could obviate the rejection of the claims (bottom of page 23 of the Office Action). Thus, amendments to claims 1, 25-26, 44-45 and 60, unambiguously recite the entire set of 8 primers.

Accordingly, withdrawal of the rejection of pending claims 1-4, 6-11, 16-17, 19-29, 31-37, 39-42, 44-57, 59-61 and 72-75 under 35 USC § 112, second paragraph is respectfully requested.

In re Application of:  
Germino et al.  
Application No.: 09/904,968  
Filed: July 13, 2001  
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PATENT  
Attorney Docket No.: JHU1680-2


### CONCLUSION

In view of the amendments and the above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicants' representative if there are any questions relating to this application.

Enclosed is Check No. 578839 in the amount of \$455.00 which consists of \$395.00 for the Request for Continued Examination fee and \$60.00 for a one-month extension of time fee. The Commissioner is hereby authorized to charge any other fees that may be associated with this communication, or credit any overpayment, to Deposit Account No. 07-1896. A duplicate copy of this transmittal is enclosed.

Respectfully submitted,

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